

**FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP**  
1100 SUPERIOR AVENUE, SUITE 700  
CLEVELAND, OHIO 44114-2518  
(216) 861-5582

**DATE:** October 1, 2002

**TO:** U.S. Patent and Trademark Office

**ATTENTION:** Supervisory Legal Instruments Examiner J. Hodge

**FACSIMILE NO.:** 1 (703) 305-7658

**FROM:** Timothy E. Nauman, Reg. No. 32,283

**RE:** Application No. 09/977,406, filed October 15, 2001  
Our Reference: CLW 2 0147

Total number of pages (including this cover sheet): 16  
Please call us immediately at (216) 861-5582 if the telecopy you receive is incomplete or illegible. Our facsimile numbers are (216) 241-1666 and (216) 241-5147.

**Ms. Hodge:**

Per our conversation, attached is the 14 page fax and our confirmation of transmission of the fax sent on September 9, 2002.

The documents accompanying this facsimile transmission include information from the firm of Fay, Sharpe, Fagan, Minnich & McKee, LLP that might be legally privileged and/or confidential. The information is intended for the use of only the individual or entity named on this cover sheet. If you are not the intended recipient, any disclosure, copying, or distribution of these documents, or the taking of any action based on the contents of this transmission, is prohibited. If you have received this transmission in error, these documents should be returned to this firm as soon as possible, and we ask that you notify us immediately by telephone so we can arrange for their return to us without cost to you.

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ACTIVITY REPORT \*\*\*  
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TRANSMISSION OK

TX/RX NO. 6919  
CONNECTION TEL 17033056384  
CONNECTION ID GRP220  
START TIME 09/09 16:15  
USAGE TIME 03'29  
PAGES 14  
RESULT OK

FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP  
1100 SUPERIOR AVENUE, 7th Floor  
CLEVELAND, OHIO 44114-2518  
(216) 861-5582

DATE: September 9, 2002  
TO: U. S. PATENT AND TRADEMARK OFFICE  
ATTENTION: LICENSING & REVIEW  
FACSIMILE NO.: 1 703 305-6384  
FROM: Timothy E. Nauman  
RE: U.S. Application Serial No. 09/977,406  
Our Reference: CLW 2 00147

Total number of pages (including this cover sheet): 14

Please call us immediately at (216) 861-5582 if the telecopy you receive is incomplete or illegible. Our facsimile numbers are (216) 241-1666 and (216) 241-5147.

Attached please find a Transmittal and five (5) Declarations Under 42 U.S.C. §2182 for U.S. Serial No. 09/977,406, filed October 15, 2001 (Seema Garde, et al.) for PHARMACEUTICAL PREPARATION AND METHODS FOR INHIBITING TUMORS.

**FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP**  
**1100 SUPERIOR AVENUE, 7th Floor**  
**CLEVELAND, OHIO 44114-2518**  
**(216) 861-5582**

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## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Seema Garde, et al.  
For : **PHARMACEUTICAL PREPARATIONS AND  
METHODS FOR INHIBITING TUMORS**  
Serial No. : 09/977,466  
Filed : October 15, 2001  
Group Art Unit : 1615  
Attorney Docket No. : CLW 2 00147

Assistant Commissioner for Patents  
Washington, D.C. 20231  
**Attention: Licensing and Review**


**TRANSMITTAL OF STATEMENTS UNDER 42 U.S.C. §2182  
(STATEMENT UNDER §152 OF THE ATOMIC ENERGY ACT)**

Dear Sir:

Responsive to the Decision on Request for Reconsideration mailed 08 August 2002, applicants submit herewith five (5) Declarations, one signed by each inventor of the subject application, in Response to Notice of Nuclear Material Contained in Application as Recited in 42 U.S.C. §2182.

Respectfully submitted,

FAY, SHARPE, FAGAN,  
MINNICH & McKEE, LLP



Timothy E. Nauman  
Reg. No. 32,283  
1100 Superior Avenue, 7th Floor  
Cleveland, Ohio 44114-2518  
(216) 861-5582

**CERTIFICATE OF FACSIMILE**

I hereby certify that this Transmittal of Statements Under 42 U.S.C. §2182 and all documents indicated therein as being enclosed, are being transmitted via facsimile to the United States Patent and Trademark Office, Washington, D.C., Attention: Licensing & Review at Final Fax No. 703/305-6384 on September 9, 2002.

By:

  
Mary M. Schriener



UNITED STATES PATENT & TRADEMARK OFFICE  
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL  
PROPERTY AND DIRECTOR OF THE UNITED STATES  
PATENT AND TRADEMARK OFFICE  
Washington, D.C. 20231

PATENT & TRADEMARK OFFICE  
**MAILED**

AUG - 8 2002

**RECEIVED**

AUG 16 2002

FAY, SHARPE, BEALL, FAGAN,  
MINNICH & MCKEE

LICENSING & REVIEW

CLW2 047

Timothy E. Nauman Esq  
Fay, Sharpe, Fagan  
Minnich & McKee, LLP  
Cleveland, OH 44114-2516

In re Application of:  
Seema Garde et al:  
For Serial No. 09/977,406

DECISION ON  
REQUEST FOR  
RECONSIDERATION

Filed: October 15, 2001

For: **PHARMACEUTICAL PREPARATIONS AND METHODS FOR INHIBITING  
TUMORS**

This is a decision on the REQUEST FOR RECONSIDERATION filed May 14, 2002,  
responding to the communication (FORM PTOL-456) mailed February 4, 2002.

703-305-6384  
LH 12

The request has been **DENIED** to the extent indicated below.

42 U.S.C. 2182 states in part "... useful in the production or utilization of special nuclear material or atomic energy". A review of the application file history reveals among other things the use of a radioactive isotope "<sup>3</sup>H" as disclosed in at least page 53 of the instant specification. Therefore under the directions from the Department of Energy (DOE) this application has been made available to them under 42 U.S.C. 2182 since the following subject matter relates to at least one of the following:

G. Materials, apparatus and methods concerning isotope and/or radioactive source technology including those utilizing (including responsive to) radioactive sources in:

- a. Life Sciences such as medicine (diagnostic and therapeutic), ecology, disease and pest control, animal husbandry, etc.
- b. Industrial processes such as food processing, sterilization, polymer production, etc.
- c. Investigations of the environment or the earth

H. Instruments employing a radioactive source and/or radioactivity detector in the operation thereof.

Applicant is reminded that a response is due within forty-five days of the mailing date of the communication (FORM PTOL-456). The communication having been mailed February 4, 2002.

  
Joanne P. Hodge  
Supervisory Legal Instruments Examiner  
Licensing and Review  
Patent Technology Center 3600

**"DOCKETED"**



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/977,406

10/15/01

GARDE, ET AL.

CLW 2 0147

EXAMINER

TIMOTHY E. NAUMAN, ESQ.

FAY, SHARPE, FAGAN, MINNICH &amp; MCKEE, LLP

1100 SUPERIOR AVENUE, 7<sup>TH</sup> FLOOR

CLEVELAND, OH 44114-2516

ART UNIT

PAPER NO.

# 13

DATE MAILED:

- 8 AUG 2002

**REQUIREMENT FOR STATEMENT UNDER §152 OF THE ATOMIC ENERGY ACT**

The subject matter of this application is considered "useful in the production or utilization of special nuclear material or atomic energy."

No patent for any invention "useful in the production or utilization of special nuclear material or atomic energy" may issue unless the applicant files a statement **WITHIN THIRTY DAYS** from request thereof by the Commissioner of Patents & Trademarks setting forth the full facts surrounding the making or conception of the invention described in the application and whether the invention or discovery was made or conceived in the course of or under any contract, subcontract, or arrangement entered into with or for the benefit of the Energy Research and Development Administration or the Department of Energy as required under section 152 of the Atomic Energy Act of 1954, 42 USC §2182.

Applicant is hereby given a period of **THIRTY DAYS** from the mailing date of this letter to file the required statement under 42 USC §2182. Failure to submit the required statement within the thirty day period will result in **ABANDONMENT** of the application. The thirty day period is fixed by §2182 of the Act and cannot be extended. Thus, no extension of this period may be obtained under either 37 CFR §1.136(a) or (b).

  
Joanne P. Hodge  
Supervisory Applications Examiner  
Special Laws Administration

Please direct all written communications regarding this matter to:  
**The Commissioner of Patents & Trademarks**  
Washington, D.C. 20231

Attention: Licensing & Review

Please direct all telephone calls regarding this matter to:  
James Samuels, (703) 305-0239